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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,548	09/30/2005	Kunio Kamata	279057US0PCT	3923

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
06/24/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/551,548	KAMATA ET AL.	
	Examiner	Art Unit	
	BAO LI	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _____ is/are rejected.

7)☐ Claim(s) *36-64* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/08/2010 has been entered. The RCE follow:

Summary

The response and amendment filed in 06/08/2010 have been noted and entered. Claims 1-35 have been amended. New claims 36-64 have been added. Claims 36-64 are pending and considered.

Claim Rejections - 35 USC § 103

1. The rejection of claims 10-13, 20, 22, 31-35 under 35 U.S.C. 103(a) as being unpatentable over Hardy et al. (Virology, 1996, Vol. 217, pp. 252-261) and Kitamoto et al. (J. Clin. Micro. 2002, Vol. 40, No. 7, pp. 2459-2465) has been removed necessitated by Applicants' amendment for cancelling all rejected claims.

2.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 36-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, Applicants do not have possession for having a composition

having pH ranging 9.0 to 10.0 comprising an alkaline buffer, an immunobilized anti-Norovirus or anti-Sapovirus antibody, a labeled anti-Norovirus antibody –or labeled anti-Sapovirus antibody, a surfactant cited a water soluble polymer cited and an animal globulin together as claims 36-54 drafted.

3. This is a new matter in that the specification does not teach that al of these ingredients present in one composition with pH 9-10. Applicants are suggested providing a support for each of the limitations cited in the new claims 36-54 to overcome the rejection.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 55 is rejected under 35 U.S.C. 102(b) as being anticipated by Hardy et al. (Virology, 1996, Vol. 217, pp. 252-261).

6. Hardy et al. teach a method for using ELISA to detect the Norovirus in a biological stool sample. the method comprises first coating the anti-norovirus antibody to ELISA plate at pH 9.6 and than loading the biological sample suspected or positively containing the Norovirus or Norovirus antigen made by recombinant DNA technique., i.e. VLP in a Tris buffer (pH 9.0). Therefore, the disclosure of the cited reference anticipates claim 55.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hardy et al. (Virology, 1996, Vol. 217, pp. 252-261) and further in view of Atmar et al. (Clin. Micro. Review 2001, Vo. 14, No. 1, pp. 15-37) for claims 56-64.

9. Hardy et al. teach a method for using ELISA to detect the Norovirus in a biological stool sample. the method comprises first coating the anti-norovirus antibody to ELISA plate at pH 9.6 and than loading the biological sample suspected or positively containing the Norovirus or Norovirus antigen made by recombinant DNA technique., i.e. VLP in a Tris buffer (pH 9.0). Hordy et al. do not teach a sandwich assay for detecting Norovirus cited in claims 56-59.

10. Atmar et al. describe diagnosis assays for detecting norovirus or sapovirus antigen in biological samples including the stool samples susceptibly infected with a norovirus or sapovirus. The assays is a regular sandwich assay or antigen capture assay comprise a microtiter plate coated with either polyclonal antisera or at least more than one monoclonal antibodies usually at alkaline condition as taught by Hardy et al. Therefore, these anti-norovirus antibodies inherently comprise all binding sites for capside protein of norovirus. The biological sample comprising susceptive norovirus or sapovirus is loaded and incubated with the coated plate and is finally detected by an anti-norovirus antibody or antisera labeled with detectable agent directly or indirectly, wherein the indirectly labeling comprises a secondary antibody against the anti-norovirus antibody (See pages 22-23). Atmar et al. conclude that the antigen capture assays using these methods improve the sensitivity for more than 20% in a large epidemiological survey. Atmar et al. do not implicitly teach the sapovirus antibody, but it is well know in the art that sapovirus has a very similar structure like Norovirus and it VLP particle that can be used for anti-sapovirus antibody with all well known technology in the art.

11. Therefore, it would have been obvious for any person ordinarily skilled in the art to be motivated for combining the method disclosed by Hardy et al and Atmar et al. for detecting Norovirus or Sapovirus by an ELISA Sandwich assay with reasonable expectation of success. Hence, the claimed invention as a whole is prima facie obvious absence unexpected results.

3.

4.

5. In the response, Applicants submit the following arguments:

6. 1). claims 10-13 and 20 have been amended to have the limitations of claims 14-19;

7. 2). There is no evidence that pH is still at 9.0 to 10.0 after the antibody and sample is 1:1000 diluted;

8. 3). Hardy is silent for the pH being 9.0 to 10.0 for the IEM assay;

9. 4). Office does not provide reasoning explaining why a 1:1000 diluted of rNV particles and antibodies would have a pH within the range of 9.0 to 10,0 required by claims 1 and 31; and

10. 5). Kitamoto is also silent about a composition having pH ranging from 9.0 to 10.0.

11. Applicants' amendment and argument have been respectfully considered; however, it is not found persuasive to overcome the rejection for the following reasons:

12. 1). Claims 1 and 31 do not have the limitations of claims 14-19 that specify the composition comprising two anti-norovirus antibodies or anti-sappovirus antibodies simultaneously present in the claimed composition, wherein one is labeled and another is immobilized

13. 2). A reasonable broadly interpretation of the scope of the claim 1 and 31 reads the citations regarding the animal globulin, surfactant as well as a water-soluble polymer are only cited as an optional choice rather then a limitation.

14. 3). According to the disclosure by Hardy, et al. in page 253, the rNV is prepared in Tris pH 9.0 and incubated with anti-norovirus antibody diluted in 1;1000. Hardy et al teach to dilute the antibody 1:1000 rather then the rNV in the IEM assay. Therefore, the assertion that the pH may be changed because the 1:1000 dilution of rNV is not applicable in view of the disclosure of the Hardy's reference.

15. 4). Scientifically, it is well known in the art, the regular procedure for doing antibody/antigen reaction, the concentration of an antibody added into a reaction mixture is usually described as a fold of a dilution to its originally stock, because the affinity of an antibody binding to an antigen depends on the affinity of an antibody binding to the antigen epitope, such as the molecular structures of the 3 CDR rather than the protein concentration of an antibody. The antibody added into the sample is always in a very small volume compared to the large volume of the sample comprising an antigen. Sometimes, the dilution is calculated based on the microliter (μl) added to the large volume such as milliliter (ml) of protein sample (1 ml equals to

1000 μl). Other the other hand, an antigen added into the reaction mixture is usually measured by a protein concentration rather than dilution.

16. 5). The reference by Nakata et al. in 1987 as Applicants pointed out does not describe the IEM method being performed at any pH. It only cites the IEM can be performed according to another reference drawn to a method for detecting Rotavirus detection by IEM rather then rNV detection.

17. Without description by Hardy et al. that the rNV is diluted with any other buffer with a low pH before incubating with an antibody, office considers the reaction mixture the IEM is conducted at pH 9-10, the reaction mixture is still considered as a composition comprising anti-norovirus antibody and a norovirus specimen in a Tris alkaline buffer at pH 9.0. See In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) [PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical. While "indirect comparisons, based on established scientific principles, can validly be applied to distinguish a claimed chemical process or product from that disclosed in the prior art," In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 432 (CCPA 1977), the comparisons must be scientifically valid. Patent owner's burden under the circumstances presented herein was described in In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows: Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on `inherency' under 35 U.S.C. § 102, or prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted]. Applicants are encouraged to provide evidence as a Declaration showing that IEM for rNV detection cannot be performed in pH 9.0 – 10.0 and it can be performed only at pH lower than 9-10.0.

18. The disclosure of Kitamoto et al. is the antibody against sappovirus ready known in the art prior to the current Application was filed. The technique for mobilizing or labeling a known antibody directed or indirectly are all well known in the art as evidenced by Hardy et al. or

Kitamoto et al. these anti-Norovirus or anti-sappovirus antibodies are all finally labeled with a detectable marker.

19. Therefore, modification of an optimal condition for using or preparing a structure and functionally already known component is generally recognized as being within the level of the ordinary skill in the art, In re Rose, 105 USPQ 237 (CCPA 1995) because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the workable ranges involves only routine skill in the art, In re Aller, 105, USPQ 233.

20. Hence, the claimed invention as a whole is still considered to be prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/
Examiner, Art Unit 1648